In the United States District Court
For the Northern District of Ohio
Western Division

UNITED STATES OF AMERICA, Plaintiff, v. SHAFFER PHARMACY, INC., Defendant.	)	CASE NO.: 3:21 CV 22 JUDGE ZOUHARY **UNDER SEAL**

DECLARATION OF CARL GAINOR

I, Carl Gainor, declare under penalty of perjury that the following statements are true and correct:

Professional and Academic Experience

1. I am currently an assistant professor of pharmacy at the University of Pittsburgh and have been since 1977. I am also an adjunct professor of pharmacy law at Belmont University in Nashville, Tennessee.

2. I am currently licensed to practice pharmacy in Pennsylvania and North Carolina.

3. I completed pre-pharmacy studies at the University of Michigan in 1963. I received my bachelor of science degree in 1966, followed by a master's degree in 1968, and a doctorate in 1972, all from the University of Pittsburgh in the study of pharmacy. I also received a law degree from the University of Pittsburgh in 1975.

4. I did a post-graduate hospital residency at the Veterans' Administration hospital system in Pittsburgh, Pennsylvania in 1967. I then practiced pharmacy as a staff pharmacist at the Montefiore Hospital in Pittsburgh, Pennsylvania from 1970 until 1976.

5. I have also practiced pharmacy as a retail pharmacist with the Thrift Drug Company in Pittsburgh, Pennsylvania, and the Kerr Drug Company in North Carolina. In addition, I worked as a part-time retail pharmacist at two independent community pharmacies in Pittsburgh, Pennsylvania.

6. As an attorney, I served as legal counsel to the Pennsylvania Pharmacists Association for approximately 25 years.

7. In my capacity as a professor of pharmacy at five schools of pharmacy over the years, I have taught thousands of students in matters of pharmacy, with an emphasis on the laws and regulations of practicing pharmacy.

8. In this capacity, I teach students the practical considerations of complying with the federal statutes and regulations pertaining to the practice of pharmacy. Chief among those statutes is the Controlled Substance Act, 21 U.S.C. § 801 et seq. ("CSA"), and the regulations promulgated under the CSA, particularly 21 C.F.R. Part 1300. These matters are central to the practice of pharmacy when dispensing controlled substances. I am familiar with the rules and regulations of the practice of pharmacy in Ohio.

9. Based on my training and experience, I am specifically familiar with 21 C.F.R. § 1306.04(a), the federal regulation governing the issuance of controlled substance prescriptions, and 21 C.F.R. § 1306.06, the federal regulation that provides that a "prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a [DEA] registered pharmacy."

Materials Reviewed

10. I was asked by the U.S. Department of Justice to review prescription dispensing records of Shaffer Pharmacy for the time period 2015 into 2020 to evaluate whether the

pharmacists filling prescriptions for controlled substances at the pharmacy were appropriately exercising their corresponding responsibility under the Controlled Substances Act and regulations to ensure the medical legitimacy of the prescriptions dispensed and dispensing controlled substances in the usual course of professional pharmacy practice.

11. The request was that I review whether the pharmacists evaluated patient prescriptions for "red flags", and if such "red flags" were evident, how did the pharmacists address these problems.

12. I was provided with various documents to review including over 3,000 prescription dispensing records obtained from the Shaffer Pharmacy's pharmacy record management software system, the ICD-10 diagnoses for the specific patients selected as examples for this report, numerous updates/newsletters from the Ohio State Board of Pharmacy many of which contained information for Ohio pharmacists on opioid dispensing, and updates from the Ohio Automated Rx Reporting System (OARRS) which discussed aspects of prescribing and dispensing controlled substances in Ohio and risks associated with opioid therapy.

13. To evaluate the actions of the pharmacists at Shaffer Pharmacy I was provided Rx30 prescription dispensing data. I reviewed this data using Excel which I sorted by patient so that the prescriptions could be reviewed as the pharmacists would have received them from the patients and processed them. In addition, I reviewed and relied on spreadsheets which had already been sorted when furnished to me. This allowed me to evaluate how the pharmacists handled various potential prescription issues, including "red flags", and possible problem patients.

Practice Standards for Retail Pharmacists

14. There are certain required steps that an Ohio pharmacist must perform on a regular basis before filling any controlled substance prescription to ensure that the prescription is written pursuant to an appropriate physician-patient relationship, is clinically appropriate and safe to dispense. Some of the things the pharmacist should review are the patient's age, gender, current or known medical conditions, drug allergies, the physician's address and specialty or area of practice, and the condition being treated to the extent that a diagnosis is provided. A pharmacist must evaluate the prescription for appropriateness of therapy and identify any therapeutic duplication, for instance, when more than one drug has been prescribed to treat the same condition. A prescription must also be reviewed to determine whether it satisfies all the requirements of a prescription. For instance, the prescription must contain the patient's name and address, the date it was issued, and the physician's name and address. It should indicate the name of the drug prescribed, the strength, dosage form, quantity prescribed, and directions for use. When the prescription is for a controlled substance, it must also contain the prescriber's DEA registration number.

15. For controlled substances, there are additional steps a pharmacist should perform to verify the legitimacy of the prescription and to prevent potential abuse and/or diversion. The pharmacist should also review the quantity of the medication prescribed; appropriate dosage; the distance of the patient's home from the physician and/or the pharmacy; trends in the physician's prescribing habits for the patient; and the number of prescribers and pharmacies the patient has used for similar medications. Schedule II controlled substances require even more scrutiny to ensure legitimacy due to the high risk of abuse and diversion. Oxycodone, morphine, hydrocodone, and other opioids are known to be commonly diverted and abused drugs in the

United States. With the rise in abuse, diversion, and drug related overdoes, such verification steps are more important than ever.

16. I am familiar with the federal requirement that a pharmacist has a "corresponding responsibility" to ensure the proper prescribing and dispensing of controlled substances (21 C.F.R. § 1306.04(a)). This is an independent responsibility of the pharmacist to ensure that prescriptions for controlled substances are legitimate. In other words, just because a licensed physician prescribed a controlled substance, does not mean that a pharmacist is obligated to fill that prescription. A reasonably prudent pharmacist in Ohio must be familiar with suspicious activity or "red flags" indicating that the controlled substances prescribed are at risk for abuse or diversion. As a pharmacist and a professor of pharmacy, I teach pharmacy students how to detect "red flags," as well as trends in pharmacy diversion and processes to resolve and limit any concerns that a pharmacist should have when presented with questionable prescriptions. Based on my experience and available public information, opioid diversion in Ohio and throughout the United States has increased significantly. In recent years, physicians have played a larger role in the diversion of controlled substances, either intentionally, or by failing to ensure that the prescriptions they issue are for legitimate medical purposes and issued in the usual course of professional practice.

17. As a pharmacist and a professor of pharmacy, I have learned to recognize various "red flags" for abuse and/or diversion in prescriptions for controlled substances, and I teach students to look for such "red flags." All competent pharmacists can and should be able to recognize "red flags" related to prescriptions for controlled substances, and pharmacists are required to do so in the usual course of pharmacy practice in Ohio and throughout the United States.

18. Generally, a "red flag" is anything about a controlled substance prescription that would cause the pharmacist to be concerned that the prescription was not issued for a legitimate medical purpose by a registered prescriber in the usual course of professional practice. Some of the red flags for diversion that all pharmacists should be familiar with include the following:

a. The prescriptions are for high dosage strengths of the drug and/or for large quantities. Opioids drugs are often referred to based on a Morphine Milligram Equivalent ("MME") value to allow comparison of potency or strength based on the relative strength of morphine across varying opioids like oxycodone, fentanyl, or hydrocodone. The CDC has indicated that any dose above 90 MME poses a risk of harm to the patient and should be accompanied by additional care, justification, and documentation. Therefore, any dose above 90 MME is potentially a "red flag" which the pharmacist should identify and resolve prior to dispensing opioids at these levels.

b. The duration of controlled substance therapy exceeds ordinary periods required for appropriate medical therapy.

c. When drugs are part of a prescription "cocktail." A prescription cocktail is any combination of drugs which, when taken together, present medical contraindications or otherwise may pose a risk of adverse health outcome to a patient. A prescription for an opioid, such as oxycodone, combined with a prescription for a benzodiazepine (anti-anxiety drug) such as alprazolam (also known by its brand name, Xanax), and possibly a skeletal muscle relaxant, such as carisoprodol (also known by its brand name, Soma) is a classic controlled substances cocktail commonly sought by drug abusers because they produce an intensified "high," but they can also be particularly deadly. The combination of an opioid, benzodiazepine, and skeletal muscle relaxant is sometimes referred to as a

"Trinity" cocktail. The combination of an opioid (depressant) and amphetamine (stimulant) is an example of generally contraindicated, conflicting, or counteracting drugs.

d. Early fills or refills of controlled substance prescriptions.

e. Patients who obtain multiple controlled substance prescriptions from multiple prescribers.

f. A prescriber may be a potential "problem prescriber" if she or he continually prescribes excessive quantities of controlled substances, especially controlled substance cocktails. When presented with a prescription from a "problem prescriber" a pharmacist should be on especially high alert for any other "red flags."

g. Multiple people, all of whom obtained similar prescriptions from the same physician and/or same clinic, arrive at the pharmacy at approximately the same time to have their prescriptions filled.

h. Patients are willing to pay large sums of cash (or write checks or use credit cards) for controlled substances, especially when the patients have insurance coverage available for the drugs.

i. Two or more controlled substance prescriptions are issued together which indicate duplicate therapy, for example, when a patient is issued two or more prescriptions known to treat the same condition in the same manner.

j. The patient's address is a significant distance from the prescriber's address and/or the pharmacy's address.

19. When confronted with one or more "red flags" concerning a prescription for a controlled substance, a pharmacist must intervene and resolve the "red flag" to determine whether or not the prescription is for a legitimate medical purpose before filling the prescription.

The pharmacist should also document his or her findings for future reference when treating the patient to assure that other pharmacists treating that patient will have the information available. The absence of any such documentation is an indication that no intervention was done to resolve the "red flag(s)."

20. Depending on the type of "red flag," there are different steps that the pharmacist can take to determine whether or not the prescription is for a legitimate medical purpose. These steps involve obtaining more information from the physician, the patient, or both. For example, in situations where a customer from out-of-town is attempting to fill a controlled substance prescription, a pharmacist should seek information from the patient as to why he or she is in the area trying to fill the prescription at this pharmacy.

21. When a pharmacist contacts a physician to address "red flags" raised by the prescription, the standard practice is for the pharmacist to document that contact and the information the pharmacist learns. Documentation noting the "red flag" and how the pharmacist handled it is good professional practice. This ensures that the information is available for other pharmacy staff in the future. Documentation should be required even in a pharmacy with only one pharmacist because perfect recall of every encounter with every patient is not realistic.

22. There are some "red flags" that a pharmacist cannot resolve even by contacting the physician, obtaining a OARRS report, or obtaining more information from the patient, such as those cases when the pharmacist has reason to believe that the physician is complicit in abuse or diversion of the controlled substance. If a "red flag" is not resolved, the pharmacist should not fill the controlled substance prescription.

23. A pharmacist may consider the patient's diagnosis in his or her attempt to resolve "red flags", thus the ICD-10 diagnosis/diagnoses for each of the specific patients selected as

examples for this Report was/were considered, but a pharmacist must always remember that the diagnosis is determined by the prescriber of the drugs. A pharmacist does not adequately assure that a prescription is for a legitimate medical purpose merely by contacting the prescriber and asking the prescriber if the drugs ordered were medically necessary. An affirmative answer from a prescriber would always be expected, and would not confirm a legitimate medical purpose. The pharmacist has an independent and corresponding responsibility to assure the legitimacy of the prescription, and this responsibility is not satisfied by merely consulting with the prescriber.

Opinions Regarding Shaffer Pharmacy

24. As requested, I reviewed thousands of prescription dispensing records covering the time period 2015 into 2020 for various patients of Shaffer Pharmacy. By the timeframe addressed in this report, 2015 to 2020, all competent pharmacists should have been well aware of the opioid abuse crisis in the U.S. This crisis was documented and discussed in pharmacy professional publications, continuing education programs, the national news media, pharmacy newsletters, and state board of pharmacy publications. Of specific relevance to this case, I was able to review multiple Newsletters and Notices from the Ohio State Board of Pharmacy for the period 2/2015 through 8/2019, and almost every such publication contained some mention or article on the drug abuse problem, advising pharmacists of their responsibilities and duties relative to the handling and dispensing of controlled substances.

25. The examples described below raise obvious "red flags" known to competent pharmacists and which should have been identified and resolved prior to dispensing the controlled substances. Ohio law and regulations require pharmacists to conduct a prospective drug utilization review to examine the appropriateness of prescription drug or controlled substance therapy prior to filling a prescription. Competent pharmacists should document in the

patient profile any comments regarding a patient's drug therapy. Based on my education, experience and expertise, a number of the prescriptions filled by Shaffer Pharmacy raised significant "red flags" that the pharmacists did not appear to resolve before providing the drugs to the patients. If the pharmacists had conducted an appropriate drug utilization review, they would have identified the "red flags," and if they appropriately documented a resolution for any "red flag" it should be contained within the records I reviewed. It is my professional opinion that the pharmacist/pharmacists at Shaffer Pharmacy should not have filled those prescriptions without obtaining information that satisfactorily resolved those "red flags" and without documenting their resolution.

Examples of such conduct are as follows:

26. With regard to patient S. M.-Q., she obtained oxycodone prescriptions from over 20 different prescribers over a period of 3 ½ years, well into 2019, by which time pharmacists across the United States were, or should have been, well aware of the drug abuse epidemic and the "red flags" that might indicate inappropriate drug usage. Not only was the duration of therapy with opioids excessive, but the dosages were dangerously high. The patient was receiving 630 MME's in April of 2016, a level that was so dangerously high that the pharmacists should have refused to fill such prescriptions without some justification that the prescriptions were for a legitimate medical purpose. Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of March, 2016 to November, 2019. Although the pharmacists entered notes into the patient's record to be aware of early fills and to accept only hard copy prescriptions, I could find no indications that the pharmacist/pharmacists intervened or obtained any legitimate medical justification for such oxycodone doses, and there is no indication that

they ever consulted the OARRS. They continued to provide the patient with high oxycodone doses into 2019 when knowledge of the risks of excessive MME's was well documented. In June of 2019 the patient was receiving over 700 MME's; and by November of 2019 the level had escalated to over 1,000. Further raising doubts about the professional conduct of the pharmacy staff was the fact that the patient was also receiving prescriptions for a benzodiazepine, a category of drug often associated with drug abuse when combined with opioids. The patient continued to receive benzodiazepines plus opioids for over 3 ½ years, well into 2019 by which time competent pharmacists were well aware of "red flags" and the drug abuse issues in the U.S. The patient had an ICD-10 Code diagnosis of "Hb-SS disease with crisis, unspecified" but it is my professional opinion that this Code would not justify the extended and excessive narcotic therapy and other drugs associated with drug abuse, nor could it be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. One final note that should have raised concerns for the pharmacists was that over 80% of all the prescriptions the patient received from Shaffer Pharmacy were for drugs that were controlled substances, and over 60% of all the prescriptions were for oxycodone. Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of April, 2016 to January, 2020.

27. With regard to patient J.M., she obtained high doses of oxycodone and morphine from Shaffer Pharmacy for over 3 ½ years, with such prescriptions continuing into January of 2020. The doses of the opioid drugs were dangerously high resulting in MME's of 390 to 450 in 2017, 345 to 390 in 2018, 450 to 630 in 2019, and 450 in January of 2020. As further evidence of failure to abide by acceptable pharmacy practices, the pharmacists regularly provided early fills

of oxycodone and morphine to the patient. The patient had an ICD-10 Code diagnosis of "Neoplasm related pain (acute) (chronic)", but it is my professional opinion that this Code alone would not justify the extended and excessive narcotic therapy, the concurrent benzodiazepines/sedatives/anticonvulsants/antidepressants, nor could it be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. It should also be noted that over 50% of all the prescriptions the patient received were for controlled substances, and that over 1/3 of all the prescriptions the patient received were for oxycodone or morphine. These dispensing practices continued into 2020, by which time competent pharmacists in the U.S. were well aware of the drug abuse crisis and the concept of "red flags." There is no indication that any pharmacist at Shaffer Pharmacy intervened or established a legitimate medical need for such excessive doses, and there was nothing in the pharmacy notes I was provided that indicated that any pharmacist at Shaffer Pharmacy ever consulted the OARRS. As indicated above, in addition to the long duration of high dose opioids, the patient also received benzodiazepines, sedatives, anticonvulsants, and anti-depressants concurrently with the opioids. This combination of drugs was a "red flag" that the pharmacist/pharmacists seemed to ignore. Such dispensing would indicate either a lack of knowledge about drug abuse and "red flags" or an indifference to the laws and regulations governing the dispensing of controlled substances. Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of April, 2016 to January, 2020.

28. With regard to patient M. J.-P., she received opioid prescriptions for 4 years without any apparent documentation to establish the legitimate medical need for such long therapy with drugs that are generally indicated for acute therapy use only. The doses were over

twice the dangerous daily dose limits, with MME's of over 200 for over 3 years, and such therapy was continued into 2020, well after pharmacists across the U.S. should have been aware of the drug abuse crisis. In addition to the opioids, the patient also was dispensed benzodiazepines, skeletal muscle relaxants, and sedatives, a modified version of the "Trinity" of drugs often seen in drug abuse cases. The patient had an ICD-10 Code diagnosis of "Sacroiliitis, not elsewhere classified", but it is my professional opinion that this Code would not justify the extended and excessive narcotic therapy as well as the modified "Trinity" of drugs, nor could it be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. It was also of note that almost 50% of all prescriptions the patient received were for oxycodone or hydrocodone, both opioids. The pharmacy's patient history notes I was provided indicated only one time a pharmacist ever consulted the OARRS during the entire 4 years of opioid therapy. All of these facts indicate that the pharmacists of Shaffer Pharmacy did not operate in an acceptable professional manner as it related to the dispensing of controlled substances. Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of March, 2016 to March, 2020.

29. With regard to patient L.A., she received oxycodone prescriptions for 5 years. As with the above-cited patients, there is no indication that the Pharmacy staff ever intervened to determine if there was a legitimate medical need for such long-term opioid therapy. For the entire 5 years of therapy the patient's daily MME consumption was 240, almost three times the accepted dangerous daily dose of 90. In addition to the opioids, the patient was also receiving from the Pharmacy other drugs often associated with drug abuse when taken with opioids. L.A. received prescriptions for skeletal muscle relaxants, sedatives, benzodiazepines, and gabapentin,

a drug cited in the last few years as being abused so often that some states have listed it as a controlled substance. The patient had an ICD-10 Code diagnosis of "Other cervical disc degeneration, unspecified cervical region", but it is my professional opinion that this Code would not justify the extended and excessive narcotic therapy and the other drugs associated with abuse, nor could it be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. Such dispensing practices by Shaffer Pharmacy indicate either a lack of recognition of "red flags" or a disregard of the corresponding responsibilities of a pharmacist relative to the dispensing of controlled substances. Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of January, 2015 to January, 2020.

30. With regard to patient S.B., this patient received schedule II-IV controlled substance prescriptions from 17 different prescribers and obtained prescriptions for Schedule II opioids from 11 different prescribers. This fact alone should have alerted the pharmacists at Shaffer Pharmacy to a potential "red flag" problem of doctor shopping by the patient, and raised questions as to the legitimate medical need for the prescriptions. The next "red flag" that the pharmacists should have recognized was the duration of the opioid therapy, which is generally indicated only for acute pain, not years of maintenance therapy. This patient received continuous prescriptions for opioids for almost 4 years, and the doses exceeded medically accepted safe levels. By the end of 2016 the patient was receiving dosages resulting in 360 MME's per day, and the levels rose to 450 in 2017 and 2018. The excessive MME's continued into 2020 at a daily level of 225. There is nothing in the Pharmacy's notes to support the need for the duration or dose of such opioids, and there is only one indication during this entire course of therapy that

the pharmacy queried the OARRS. The patient had an ICD-10 Code diagnosis of "Cough variant asthma", but it is my professional opinion that this Code would not justify the extended and excessive narcotic therapy and other drugs associated with drug abuse, nor could it be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. It is also troubling that the dispensing continued into 2020 when the drug abuse crisis had been well documented and publicized. To make matters worse, during the opioid therapy the pharmacy also filled prescriptions for benzodiazepines, skeletal muscle relaxants, and later in the course of therapy, gabapentin, all drugs recognized as potential indicators of drug abuse when taken together with opioids (the "Trinity"). A final observation on problems with the pharmacy practice at Shaffer Pharmacy was that the patient often received early fills of schedule II-IV controlled substance prescriptions during 2016 and continuing into 2020. An occasional early fill is to be expected, but when it becomes a pattern, a problem is evident. Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of March, 2016 to January, 2020.

31. With regard to patient M.K., this patient presented a pattern of drug use/abuse similar to many of the other noted patients. A significant number of the prescriptions for this patient were written by a practitioner who appears to display a pattern of excessive opioid prescribing. The pharmacists should have been aware of this type of dubious prescribing, and have questioned the medical necessity of the opioid prescriptions for this patient. The prescribing also included orders for benzodiazepines concurrent with the opioid therapy, thereby further raising concerns for the medical appropriateness of the prescriptions. The duration of therapy spanning 4 years of opioids plus benzodiazepines was excessive without explanation, and the

Pharmacy's notes indicated only one time in the four-year span when someone from Shaffer Pharmacy consulted with the OARRS. The excessive dose of the opioids was another "red flag" that should have caused the pharmacist/pharmacists to question the prescriptions. The MME's this patient was receiving started at 180, which is twice the dangerous level established by the CDC. During 2016 through March of 2020 the patient received MME's of 195 to 390. What is especially troubling is that the highest MME's occurred in 2020 when the drug abuse crisis was well known and publicized. The patient had an ICD-10 Code diagnosis of "Other cervical disc displacement, mid-cervical region", but it is my professional opinion that this Code would not justify the extended and excessive narcotic therapy and benzodiazepines, nor could it be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. A final note on problems with the dispensing history for this patient is the fact that the patient received periodic early fills of 2 to 4 days of morphine for over 3 years. The inescapable conclusion is that the pharmacy ignored or disregarded numerous "red flags" for years when dispensing dangerous drugs to this patient. Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of March, 2016 to March, 2020.

32. With regard to patient N.W., this patient received some of the highest doses of opioids of any of the patients I reviewed, and the therapy continued for almost 4 years. The pharmacy notes are devoid of any explanation for the dangerously high, long-term doses. The pharmacists only queried the OARRS database one time during the four years of therapy, and that did not occur until December of 2019. The patient was receiving opioid prescriptions from 4 different prescribers, and almost 70% of all the drugs the patient obtained from the pharmacy were for Schedule II opioids. The patient had an ICD-10 Code diagnosis of "Other chronic pain",

but it is my professional opinion that this Code would not justify the extended and excessive narcotic therapy, nor could it be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. It was also of concern that the patient received early fills of opioid prescriptions by 1 to 3 days for a period of over 3 years. These were serious "red flags", and I could find no indication that the pharmacists addressed or resolved them. To understand the severity of the dispensing pattern for this patient it is important to remember that the CDC guidelines indicate that opioid doses above 90 MME's are considered dangerous. Patient N.W. was receiving dosages resulting in MME's over 1,900 and those doses continued for almost 4 years into 2020, at which time the drug abuse crisis was well known and publicized. Doses this high are generally reserved for only the most serious acute pain, such as terminal cancer, but such patients seldom survive for almost 4 years. Doses this high should have been explained with some type of documentation in the pharmacy notes, and the fact that the OARRS was consulted in December of 2019 would seem to indicate that the pharmacists finally had some concerns as to the patient's drug consumption but continued to fill opioid prescriptions into February of 2020. Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of March, 2016 to February, 2020.

33. With regard to patient L.C., she followed the pattern of many of the other patients of Shaffer Pharmacy by receiving prescriptions for high dose opioids for an extended period of time, including 2019 and into 2020, when the drug abuse crisis was well known to all competent pharmacists. During the course of therapy that I examined from 2016 into 2019 the patient received doses with MME's of between 350 and almost 900. Even as late as February of 2020 she was receiving MME's of almost 150. These doses far exceeded the Government's dangerous

level of 90. Two other factors with this patient were especially troubling. The first was that almost 90% of all the prescriptions this patient received during the 4 years of therapy were for Schedule II opioids. The second was that she was receiving fentanyl lozenges, a powerful opioid drug approved only for treating breakthrough pain in cancer patients while this patient was receiving it for apparent maintenance therapy. I could find nothing in the pharmacy notes to explain this inappropriate therapy or that the pharmacists were even concerned. The notes did not indicate even one instance when the OARRS database was consulted. The patient had ICD-10 Code diagnoses of "Sacroiliitis, not elsewhere classified" and "Unspecified osteoarthritis, unspecified site", but it is my professional opinion that these Codes would not justify the extended and excessive narcotic therapy, nor could they be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. This patient's drug history appears to demonstrate a lack of knowledge of "red flags" by the pharmacists at Shaffer Pharmacy or an indifference to a pharmacist's corresponding responsibility when dispensing controlled substances. Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of March, 2016 to February, 2020.

34. With regard to patient C.S., this patient's drug history demonstrated various "red flags" that went unnoticed or ignored by the pharmacists at Shaffer Pharmacy. The patient received long-term opioid therapy for over 3 years at excessive doses without any documented medical need justification. During the entire therapy there appeared to be only one query of the OARRS database, and that query did not occur until January of 2020 after over 3 years of therapy. During 2016 and 2017 the patient was receiving opioid doses resulting in MME's of 900 to 1,500, well over ten times the "dangerous" dose levels. In 2018 the doses dropped to 140 to

260, still well above the recommended safe levels, and even in December of 2019 the doses were at an MME of 150. Other "red flags" were the fact that the patient was concurrently receiving benzodiazepines during the opioid therapy, a possible indicator of drug abuse; that the patient received an amphetamine drug, a stimulant, for over a year in 2019 into 2020; and that the patient regularly received early fills by 1 to 3 days of opioid drugs from mid-2016 to late 2019, a period of over 3 years. The patient had an ICD-10 Code diagnosis of "Chronic pain syndrome", but it is my professional opinion that this Code would not justify the extended and excessive narcotic therapy and the other drugs often associated with drug abuse , nor could it be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. Finally, these abuses continued into 2020 by which time the drug abuse crisis was, or should have been, well known by pharmacists. Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of April, 2016 to March, 2020.

35. With regard to patient K.K., this patient's therapy exhibited numerous "red flags" that either went unnoticed or ignored by the pharmacists at Shaffer Pharmacy. She obtained schedule II-IV controlled substance prescriptions from 21 different prescribers over a period of 4 years. She obtained buprenorphine prescriptions from 5 different prescribers. During the time frame I evaluated, she obtained an array of controlled substances and other drugs often associated with drug abuse, including oxycodone, fentanyl, morphine, hydrocodone, buprenorphine, benzodiazepines, skeletal muscle relaxants, sedatives, stimulants, and gabapentin. The opioid therapy continued for 4 years, and the other drugs were prescribed intermittently over that 4-year period. None of these "red flags" seemed to generate any intervention or investigation by the pharmacists at Shaffer Pharmacy. The patient had an ICD-10

Code diagnosis of "Opioid dependence", but it is my professional opinion that this Code would not justify the extended and excessive narcotic therapy and the other drugs associated with drug abuse, nor could it be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. The pharmacy notes indicate only one query of the OARRS database, and that query did not occur until April of 2020, after 4 years of therapy. These problems continued into 2019 and 2020, after competent pharmacists in the U.S. were well aware of the drug abuse crisis and the need to address "red flags." Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of April, 2016 to April, 2020.

36. With regard to patient T.S., this patient's drug history demonstrated various "red flags" that went unnoticed or ignored by the pharmacists at Shaffer Pharmacy. The patient received opioid therapy that lasted for over 2 ½ years. The therapy provided excessively high MME's which were consistently above 330 for the entire 2 ½ years of therapy. In addition to the opioid therapy, the patient also received concurrent benzodiazepines, a drug often associated with drug abuse when combined with opioid therapy. The patient sometimes received early fills of her opioids, and it should have been of concern to the pharmacists that approximately 40% of all the prescriptions the patient received were for oxycodone. These prescriptions raised various "red flags" which do not appear to have been recognized or addressed by the pharmacists at Shaffer Pharmacy until October of 2019 when the pharmacy notes show "death in family but discussed dosage reduction today". This was also the first date the pharmacists consulted the OARRS. At this point the therapy had already continued for 2 ½ years. The patient had an ICD-10 Code diagnoses of "Chronic pain syndrome" and "Other intervertebral disc displacement,

lumbar region", but it is my professional opinion that these Codes would not justify the extended and excessive narcotic therapy and the benzodiazepines, nor could they be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. These problems continued into 2019, well after competent pharmacists in the U.S. were well aware of the drug abuse crisis and the need to address "red flags." Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of April, 2017 to January, 2020.

37. With regard to the patient J.J., this patient's therapy, as with the other patients discussed, consisted of long-term excessive dose opioids coupled with prescriptions for benzodiazepines, skeletal muscle relaxants, and gabapentin, combinations known to be favored by drug abusers. The opioid therapy continued for 3 years, and the patient continually received dosages resulting in MME's between 275 and 375, well above the CDC's "dangerous" level of 90. The patient had ICD-10 Code diagnoses of "Radiculopathy, lumbar region" and "Spinal stenosis, site unspecified", but it is my professional opinion that these Codes would not justify the extended and excessive narcotic therapy and the other drugs associated with abuse, nor could they be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. It is troubling that the pharmacists at Shaffer Pharmacy only consulted the OARRS once, that being on 10/23/18, yet continued to dispense questionable prescriptions through February of 2019. In early February 2019 the patient was still receiving dosages resulting in MME's of 285. These problems continued into 2019 after competent pharmacists in the U.S. were well aware of the drug abuse crisis and the need to address red flags. Based upon the materials I have reviewed in this case, I could find no legitimate medical

use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of March, 2016 to March 2019.

38. With regard to patient R.K., her therapy differed from most of the other patients reviewed as she received predominately buprenorphine, a drug approved for detoxification and maintenance of opioid drug addiction, for a period of 4 years. Without any explanation in the Pharmacy's notes, in May-June of 2016 and in March-April of 2020 she also received prescriptions for oxycodone and hydrocodone. Such conflicting therapy raised a "red flag" which the pharmacists apparently did not resolve. The patient had an ICD-10 Code diagnosis of "Opioid dependence, uncomplicated" which would seem to justify the buprenorphine therapy, but it is my professional opinion that this Code would not justify the prescriptions for oxycodone and hydrocodone, nor could it be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. Especially troubling was the fact that the pharmacists did not consult the OARRS until 3/25/2020, after almost 4 years of therapy. Even if the pharmacists had ignored the patient's drug profile kept at the pharmacy, they would have learned of the long-term buprenorphine therapy through the OARRS consult, yet they then elected to dispense oxycodone on that day and again on 4/1/2020 while continuing to dispense buprenorphine. An overview of the patient's prescription history disclosed that 90% of all prescriptions the patient received from Shaffer Pharmacy were for controlled substances. This history should have alerted the pharmacists to various "red flags," yet it appears that the pharmacists failed to recognize the problems or chose to ignore them. Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of April, 2016 to April, 2020.

39. With regard to patient D.B., his therapy, like many other patients of Shaffer Pharmacy, consisted of long-term, high-dose opioid therapy without any apparent medical justification. This treatment continued into 2020, by which time all competent pharmacists in the U.S. were acutely aware of the drug abuse crisis and the need to identify and address "red flags" which are indicative of possible drug abuse and invalid prescriptions. The patient was receiving concurrent fentanyl and hydrocodone prescriptions from March of 2016 until March of 2020, a period of 4 years, with continuing MME's exceeding 140. In addition to the opioid prescriptions, the patient was also receiving prescriptions for benzodiazepines, antidepressants and stimulants. The patient had an ICD-10 Code diagnosis of "Chronic pain syndrome", but it is my professional opinion that this Code would not justify the extended and excessive narcotic therapy and the other drugs associated with drug abuse, nor could it be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. Such a combination of drugs with the duration of therapy should have alerted the pharmacists to possible or probable drug abuse, yet they continued to dispense these prescriptions for over 3 years. It is troubling that the pharmacists appear to have consulted the OARRS only one time in the entire 4 years of therapy, and that not occurring until 3/31/2020. The record seems to establish that the pharmacists either were oblivious to the potential for drug abuse and "red flags" or that they chose to ignore their professional and legal obligations. Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of March, 2016 to March, 2020.

40. With regard to patient E.H., she received prescriptions from 9 different prescribers resulting in 3 ½ years of high-dose opioid therapy. Additionally, she also received

concurrent prescriptions for benzodiazepines and antidepressants. These "red flags" should have alerted the pharmacists at Shaffer Pharmacy of possible drug abuse and prescriptions that were not written for a legitimate medical use. It appears that the pharmacists either ignored or did not recognize the "red flags" created by such long-term, high-dose opioid therapy coupled with other drugs indicating possible drug abuse, and prescriptions lacking a legitimate medical use. The doses of the opioids she received resulted in the patient receiving MME's of over 500 for over 3 ½ years. This level far exceeds the CDC's "dangerous" dose level of 90. The patient had ICD-10 Code diagnoses of "Vitamin D deficiency, unspecified", "Chronic pain syndrome" and "Essential (primary) hypertension" but it is my professional opinion that these Codes would not justify the extended and excessive narcotic therapy and the other drugs associated with abuse, nor could they be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. Further evidence of disregarding the regulations and professional responsibilities is the fact that the pharmacists often provided early fills of prescriptions during the entire course of therapy. This type of conduct by the pharmacists continued throughout 2019, by which time they knew or should have known of the drug abuse epidemic in the U.S. and the concept of" red flags". Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of March, 2016 to December, 2019.

41. With regard to patient E.C., the pharmacists at Shaffer Pharmacy should have become concerned with the number of prescribers that the patient was visiting to obtain prescriptions for controlled substances. During the period of March, 2016 and August, 2019 the patient obtained schedule II-IV controlled substance prescriptions from 16 different prescribers with 11 of those prescribers providing Schedule II prescriptions for fentanyl, oxycodone, and

amphetamine. This prescribing pattern continued for over 3 years with prescriptions being filled for opioids, amphetamines, antidepressants, sedatives, and anticonvulsants. This "modified Trinity" of possible drugs being abused raised serious "red flags" that the pharmacists either did not recognize or seem to have ignored. There is nothing in the pharmacy notes I was able to review to explain or justify providing the patient with this combination of drugs or to verify a legitimate medical use for the drugs. The patient had an ICD-10 Code diagnosis of "Chronic fatigue, unspecified", but it is my professional opinion that this Code would not justify the extended and excessive narcotic therapy and the other drugs associated with drug abuse, nor could it be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. The pharmacists apparently only consulted the OARRS one time in the entire course of therapy, and that was not done until 4/2/2020 after 4 years of therapy. As with most of the other problem patients, this troubling pattern of dispensing continued into late 2019, by which time all competent pharmacists were aware of the drug abuse crisis in the U.S. and the need to address "red flags" before filling a prescription. Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of March, 2016 to August, 2019.

42. With regard to patient D.V., the pharmacists at Shaffer Pharmacy provided the patient with an unusual and troubling array of controlled substances and other drugs often associated with drug abuse. This pattern of dispensing continued from at least early 2016 until late 2019 or early 2020 with 74% of all the prescriptions the patient received being controlled substances. For the period of March 2016 until March of 2018, 93% of all the prescriptions the patient received were for Schedule II opioids. Of great concern was the dispensing of

prescriptions for Subsys, a powerful and very expensive fentanyl product approved only for the treatment of breakthrough pain in cancer patients. By early 2018 five qui tam lawsuits accusing the manufacturer of violating the civil False Claims Act had been filed, and the questionable validity of many Subsys prescriptions was well publicized. In spite of the wide dissemination of this information in the pharmacy community, Shaffer Pharmacy continued to honor prescriptions for Subsys for this patient until October or November of 2018. In addition to the questionable opioid prescriptions, Shaffer Pharmacy also provided the patient with benzodiazepines and antidepressants, drugs often associated with drug abuse when combined with opioids. As might be expected with such therapy, the opioid doses the patient received resulted in excessive MME's. From March of 2016 through March of 2018 the patient received between 300 and 500 MME's and even in November of 2019 the patient was receiving 120 MME's. It should also be noted that the pharmacy periodically provided buprenorphine without naloxone from late 2018 into early 2020, but also periodically provided oxycodone during this same period. No explanation was provided for this therapy, thus raising the question of whether the drugs were being used for a legitimate medical purpose. The patient had an ICD-10 Code diagnosis of "Chronic pain syndrome", but it is my professional opinion that this Code would not justify the extended and excessive narcotic therapy and the other drugs associated with drug abuse, nor could it be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. As with many other patients at Shaffer Pharmacy, these potential problems continued into 2019 and 2020 at which time all competent pharmacists were well aware of the drug abuse crisis in the U.S. as well as the need to recognize "red flags" and to intervene before filling such prescriptions. Based upon the materials I have reviewed in this case,

I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of March, 2016 to January, 2020.

43. With regard to patient T.S., I observed the same troubling dispensing patterns found with most of the patients analyzed in this report. The patient received long-term, high-dose opioid therapy from April 2016 through March 2020, a period of 4 years, without any indication of the medical justification for or legitimacy of such prescriptions. The patient received doses of opioids during the entire 4-year period that resulted in MME's of 760, a level that is unreasonably high and dangerous. As with other patients utilizing this pharmacy, T.S. also received benzodiazepines and antidepressants, drugs that when combined with opioid therapy are often associated with drug abuse. The patient had ICD-10 Code diagnoses of "Lumbago with sciatica, right side" and "other chronic pain", but it is my professional opinion that these Codes would not justify the extended and excessive narcotic therapy and the other drugs associated with abuse, nor could it be used to satisfy the pharmacists' independent duty to assure that the drugs were for a legitimate medical purpose. This dispensing pattern continued into 2020, well after all competent pharmacists were aware of the drug abuse crisis in the U.S. as well as the need to recognize red flags and intervene before filling such prescriptions. Based upon the materials I have reviewed in this case, I could find no legitimate medical use for the schedule II-IV controlled substance prescriptions dispensed to this patient in the timeframe of April, 2016 to March, 2020.

44. With regard to patient J.L., this patient was not receiving excessive long-term opioid therapy. J.L. did have a modest number of prescriptions for low-dose hydrocodone and multiple prescriptions for lorazepam, a benzodiazepine, but the therapy did not raise any serious "red flags" as were noted with the prior 18 patients. The patient had an ICD-10 Code diagnosis

of "Anxiety disorder, unspecified", and this was one of the only diagnostic codes that would appear to justify the drug therapy dispensed. J.L. also received many prescriptions for non-controlled drugs, a pattern more typical of patients receiving drugs for legitimate medical uses.

45. The final patient profile I reviewed was troubling because of the exceptionally excessive doses of narcotics dispensed coupled with a myriad of other drugs associated with drug abuse when taken with opioids, but also the fact that this was a terminal cancer patient. The patient had an ICD-10 Code diagnosis of "Malignant neoplasm of hypopharynx, unspecified", but the duration and excessive doses of narcotics prescribed as well as the other drugs dispensed would require an in-depth analysis of the patient's condition to resolve the significant "red flags" that existed. In 2017 the patient, K.F., was receiving Subsys, a drug reserved for breakthrough pain in cancer with concurrent oxycodone and fentanyl patches. This combined narcotic therapy resulted in MME's of between 400 and 800 in 2017, and escalated dramatically to between 1,000 and 2,000 in 2018 into 2019. The patient was also receiving skeletal muscle relaxants, anti-psychotics, anti-depressants, sedatives, and gabapentin, all drugs associated with drug abuse when taken with opioids. The dosing, strength, duration, and combination of drugs Shaffer Pharmacy dispensed to K.F. raises significant red flags. Subsys, for example, poses significant dangers when used in combination with benzodiazepines and other central nervous system depressants. The patient passed away in 2019 from cancer. Absent the terminal cancer diagnosis, this dispensing pattern would have raised great concerns as to the legitimacy of the drug therapy and the conduct of the pharmacists, but since the pharmacists noted in their records that the patient was a cancer patient, I cannot fault providing the patient with whatever palliative care was needed to mitigate his pain and suffering. I did find it illuminating that the pharmacists at Shaffer Pharmacy did note this patient's diagnosis in their records thereby establishing that

they knew how to document serious medical conditions which might resolve red flags. Had such conditions existed with the prior patients whose drug therapy I reviewed, I see no reason why the pharmacists would not have documented the conditions to establish that the red flags had been recognized and resolved, but such documentation was lacking for each of the other individuals except one.

46. In summary, it is my professional opinion that, based on the prescription dispending records which I reviewed, Shaffer Pharmacy was not dispensing controlled substances in accordance with recognized minimum professional standards for the practice of pharmacy. The pharmacists at Shaffer Pharmacy failed to identify or resolve numerous obvious "red flags" or they ignored the fact that inappropriate prescriptions were presented to them. The pharmacists also failed to comply with their independent obligation to ensure the medical legitimacy of the prescriptions they dispensed as required by their corresponding responsibility. This pattern of dispensing was common for over 4 years with numerous patients and thousands of prescriptions, and shows an egregious disregard for the rules of appropriate and legal pharmacy practice.

Executed on December 18, 2020.

Carl Gainor, Ph.D., J.D.